UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

FERRING B.V., Plaintiff, vs. APOTEX, INC. et al., Defendants.	3:13-cv-00595-RCJ-VPC **ORDER**

The Court recently held a bench trial on four cases (the "Consolidated Cases") arising out of several defendants' manufacture and prospective sale of (and applications to the Food and Drug Administration ("FDA") to manufacture and sell) generic versions of tranexamic acid tablets, a drug patented by the plaintiff. The present case is related to the Consolidated Cases but was not filed until October 25, 2013 and was not tried together with them. Pending before the Court is Plaintiff's Motion for Temporary Restraining Order and Order to Show Cause ("TRO") (ECF No. 31). For the reasons given herein, the Court grants the motion in part. For the reasons given herein, the Court denies a TRO but will order Plaintiffs to show cause why a preliminary injunction should not issue.

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I. FACTS AND PROCEDURAL HISTORY

These five related cases arise out of the alleged infringement of Plaintiff Ferring B.V.'s ("Ferring") tranexamic acid-related patents: (1) U.S. Patent No. 7,947,739 for tranexamic acid tablets sold under the trademark Lysteda® (the "'739 Patent"), (*see* Compl. ¶¶ 13–17, July 7, 2011, ECF No. 1 in Case No. 3:11-cv-481; Compl. ¶¶ 9–13, July 8, 2011, ECF No. 1 in Case No. 3:11-cv-485); (2) U.S. Patent No. 8,022,106 for tranexamic acid formulations and methods of treating menorrhagia therewith (the "'106 Patent"), (*see* Compl. ¶¶ 13–17, Nov. 25, 2011, ECF No. 1 in Case No. 3:11-cv-00853; Compl. ¶¶ 9–13, Nov. 25, 2011, ECF No. 1 in Case No. 3:11-cv-00854); and (3) U.S. Patent No. 8,487,005 for tranexamic acid formulations and methods of treating menorrhagia therewith (the "'005 Patent"), (*see* Compl. ¶¶ 9–13, Oct. 25, 2013, ECF No. 1). In the '481 and '485 Cases, respectively, Ferring sued several Watson Labs entities (collectively, "Watson Defendants") and several Apotex entities (collectively, "Apotex Defendants") in this Court for infringing the '739 Patent. In the '853 and '854 Cases, respectively, Ferring sued several Watson Defendants and several Apotex Defendants in this Court for infringing the '106 Patent. In the present case, Ferring has sued Apotex Defendants for infringing the '005 Patent.

The Court has consolidated the cases, except the present case, with the '481 Case as the lead case. In the Consolidated Cases, the Court ruled on several pre-trial motions, held a Markman hearing, issued a claim construction order, held a bench trial, and gave its findings of fact and conclusions of law from the bench, requesting counsel to draft a written order. The parties have since filed several motions disputing the language of the proposed order, and the Court has held a hearing to clarify its instructions.

II. LEGAL STANDARDS

Under Fed. R. Civ. P. 65(b), a plaintiff must make a showing that immediate and irreparable injury, loss, or damage will result to plaintiff without a temporary restraining order. Temporary restraining orders are governed by the same standard applicable to preliminary injunctions. *See Cal. Indep. Sys. Operator Corp. v. Reliant Energy Servs., Inc.*, 181 F. Supp. 2d 1111, 1126 (E.D. Cal. 2001) ("The standard for issuing a preliminary injunction is the same as the standard for issuing a temporary restraining order."). The standard for obtaining ex parte relief under Rule 65 is very stringent. *Reno Air Racing Ass'n v. McCord*, 452 F.3d 1126, 1130 (9th Cir. 2006). The temporary restraining order "should be restricted to serving [its] underlying purpose of preserving the status quo and preventing irreparable harm just so long as is necessary to hold a hearing, and no longer." *Granny Goose Foods, Inc. v. Bhd. of Teamsters & Auto Truck Drivers Local No. 70*, 415 U.S. 423, 439 (1974).

The Court of Appeals in the past set forth two separate sets of criteria for determining whether to grant preliminary injunctive relief:

> Under the traditional test, a plaintiff must show: (1) a strong likelihood of success on the merits, (2) the possibility of irreparable injury to plaintiff if preliminary relief is not granted, (3) a balance of hardships favoring the plaintiff, and (4) advancement of the public interest (in certain cases). The alternative test requires that a plaintiff demonstrate either a combination of probable success on the merits and the possibility of irreparable injury or that serious questions are raised and the balance of hardships tips sharply in his favor.

Taylor v. Westly, 488 F.3d 1197, 1200 (9th Cir. 2007). "These two formulations represent two points on a sliding scale in which the required degree of irreparable harm increases as the probability of success decreases." *Id.*

The Supreme Court recently reiterated, however, that a plaintiff seeking an injunction must demonstrate that irreparable harm is "likely," not just possible. *Winter v. NRDC*, 555 U.S. 7, 19–23 (2008) (rejecting the Ninth Circuit's alternative "sliding scale" test). The Court of Appeals has recognized that the "possibility" test was "definitively refuted" in Winter, and that "[t]he proper legal standard for preliminary injunctive relief requires a party to demonstrate 'that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest.'" *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1127 (9th Cir. 2009) (quoting *Winter*, 129 S. Ct. at 374) (reversing a district court's use of the Court of Appeals' pre-*Winter*, "sliding-scale" standard and remanding for application of the proper standard).

A Court of Appeals ruling relying largely on the dissenting opinion in *Winter* parsed the language of *Winter* and subsequent Court of Appeals rulings and determined that the sliding scale test remained viable when there was a lesser showing of likelihood of success on the merits amounting to "serious questions," but not when there is a lesser showing of likelihood of irreparable harm. *See Alliance for the Wild Rockies v. Cottrell*, 632 F.3d 1127, 1134 (9th Cir. 2011). This case presents some difficulty in light of *Winter* and prior Court of Appeals cases. To the extent *Cottrell*'s interpretation of *Winter* is inconsistent with *Selecky*, *Selecky* controls. *See Miller v. Gammie*, 335 F.3d 889, 899 (9th Cir. 2003) (en banc) (holding that, in the absence of an intervening Supreme Court decision, only the en banc court may overrule a decision by a three-judge panel). In any case, the Supreme Court stated in *Winter* that "[a] plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his

favor, and that an injunction is in the public interest." *Winter*, 555 U.S. at 20 (citing *Munaf v. Geren*, 128 S. Ct. 2207, 2218–19 (2008); *Amoco Prod. Co. v. Gambell*, 480 U.S. 531, 542 (1987); *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311–12 (1982)) (emphases added). The test is presented as a four-part conjunctive test, not as a four-factor balancing test, and the word "likely" modifies the success-on-the-merits prong in exactly the same way it separately modifies the irreparable-harm prong. In rejecting the sliding-scale test, the *Winter* Court emphasized the fact that the word "likely" modifies the irreparable-injury prong, *see id.* at 22, and the word modifies the success-on-the-merits prong the same way, *see id.* at 20. In dissent, Justice Ginsburg opined that she did not believe the Court was abandoning the rule that it was permissible to "award[preliminary injunctive] relief based on a lower likelihood of harm when the likelihood of success is very high." *Id.* at 51 (Ginsburg, J., dissenting). But Justice Ginsburg, like the majority, did not address whether she believed relief could be granted when the chance of success was less than likely. A "lower likelihood" is still some likelihood. We are left with the language of the test, which requires the chance of success on the merits to be at least "likely."

In summary, to satisfy *Winter*, a movant must show that he is "likely" to succeed on the merits. According to a layman's dictionary, "likely" means "having a high probability of occurring or being true." Merriam–Webster Dictionary, http://www.merriam-webster.com/dictionary/likely. Black's defines the "likelihood-of-success-on-the-merits test" more leniently as "[t]he rule that a litigant who seeks [preliminary relief] must show a reasonable probability of success . . . ." Black's Law Dictionary 1012 (9th ed. 2009). The Court must reconcile the cases by interpreting the *Cottrell* "serious questions" requirement to be in harmony with the *Winter*/*Selecky* "likelihood" standard, not as being in competition with it. "Serious questions

going to the merits" must therefore mean that there is at least a reasonable probability of success on the merits. "Reasonable probability" appears to be the most lenient position on the sliding scale that can satisfy the requirement that success be "likely."

III. DISCUSSION

In the present case, Ferring has asked the Court for a TRO to prevent Apotex Defendants from selling generic tranexamic acid tablets pursuant to ANDA No. 202286, which, according to Ferring, permits infringement of the '005 Patent. In the Consolidated Cases, the Court indicated at the conclusion of trial that Apotex Defendants had not actually infringed and that the Court would rule that Apotex Defendants' ANDA would not permit infringement if amended according to specified parameters. Ferring argues in the present motion that the agreed-upon amendment leaves Apotex Defendants' permissions from the FDA under the ANDA within the scope of Ferring's '005 Patent at issue in the present case, because Claim 1 of the '005 Patent does not contain a limitation requiring "less than about 70% by weight of the tranexamic acid or a pharmaceutically acceptable salt thereof released at about 45 minutes," as the relevant claims in the '739 and '106 Patents do. Apotex Defendants' amendment of the ANDA to permit only generic tranexamic acid tablets that would release at least 75% within 45 minutes avoids infringement of the '739 and '106 Patents, but that limitation does not avoid infringement of the '005 Patent. The release limitations of the '005 Patent are "less than about 40% . . . at about 15 minutes" and "not less than about 50% . . . at about 90 minutes." Apotex Defendants' ANDA Supplement does not address these time points, and Apotex Defendants could infringe if they exercised their full permissions under the ANDA, even as amended. Ferring therefore requests a TRO to prevent Apotex from selling or offering for sale its generic tranexamic tablets.

Although it is possible that Apotex Defendants could produce tablets that infringe the '005 Patent if they exercised their full permissions under the ANDA, as amended, there is no substantial evidence presented at this time that they intend to do so. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) ("We conclude that, especially in a case such as this, involving a compound capable of existing in various forms, the statute requires an infringement inquiry focused on what is likely to be sold following FDA approval. This inquiry must be based on all of the relevant evidence, including the ANDA. As is well-established for infringement actions brought under § 271, a patentee seeking relief under § 271(e)(2) must prove by a preponderance of the evidence that what is to be sold will infringe. That burden is not shifted under § 271(e)(2)." (citation omitted)). Ferring has not provided any evidence that Apotex Defendants intend to produce or offer for sale tablets or other products that would infringe the '005 Patent. Ferring simply argues that "Apotex's ANDA Supplement would allow for the production of generic tranexamic acid tablets meeting the remaining limitation of claim 1 of the '005 patent, the dissolution limitation." (*See* Mot. TRO 14:5–8, ECF No. 31). Ferring argues in several places how the ANDA "would allow" Apotex Defendants to infringe. (*See id.* 14:5, 14:23, 15:5, 15:12–13).

However, a recent opinion distinguished *Glaxo*, noting that "if an ANDA specification defines a compound such that it meets the limitations of an asserted claim, then there is almost never a genuine issue of material fact that the claim is infringed." *Sunovion Pharm., Inc. v. Teva Pharm. USA, Inc.*, 731 F.3d 1271, 1280 (Fed. Cir. 2013). The *Sunovion* court noted that in *Glaxo*, it had affirmed the district court's non-infringement finding because the ANDA at issue was unclear as to whether a particular form of the compound was covered, and the plaintiff had not shown that it would actually be sold. *See id.* at 1279; *Glaxo*, 110 F.3d at 1569 ("Since the

compound for which approval is sought is that which is expected to be marketed, the purpose of the submission of the ANDA is to sell that well-defined compound and the ultimate question of infringement is usually straightforward. However, in this case, where the subject matter is a compound capable of existing in multiple crystalline forms, or mixtures thereof, the ultimate question of infringement is not so simple. The FDA's interest in fixing the exact nature of such a product to be sold, in discharging its own responsibility to ensure the purity, efficacy, and safety of the product, may cause the nature of the product originally applied for to differ somewhat from that ultimately approved.").

Here, there is no confusion as to the nature and scope of the chemical compound covered by the ANDA. Here we have a simple matter of comparing mathematical ranges of dissolution rates under the Patents and the ANDA. Under *Sunovion*, a district court need not conduct a *Glaxo* inquiry if it is clear that the ANDA permits infringement. *Sunovion*, 731 F.3d at 1279 (citing *Abbott Labs. v. TorPham, Inc.*, 300 F.3d 1367, 1373 (Fed. Cir. 2002) ("Because drug manufacturers are bound by strict statutory provisions to sell only those products that comport with the ANDA's description of the drug, an ANDA specification defining a proposed generic drug in a manner that directly addresses the issue of infringement will control the infringement inquiry.")). The question under the present motion is whether it is clear on the face of the ANDA, as amended, that the compound Apotex Defendants seek the FDA's approval to market would still violate the '005 Patent. As analyzed, *supra*, according to the relevant limitations, the ANDA, as amended, still permits infringement of the '005 Patent on its face.

The *Sunovion* court ruled that if it is clear that an ANDA would permit infringement, there has been infringement under subsection (e)(2), even if no traditionally recognized "actual" infringement has yet occurred. *See id.* at 1278 ("Although no traditional patent infringement has occurred until a patented product is made, used, or sold, under the Hatch–Waxman framework,

the filing of an ANDA itself constitutes a technical infringement for jurisdictional purposes. But the ultimate infringement question is determined by traditional patent law principles and, if a product that an ANDA applicant is asking the FDA to approve for sale *falls within the scope of* an issued patent, a judgment of infringement must necessarily ensue." (emphasis added; citation omitted)). The *Sunovion* court was unimpressed with the argument that one could avoid a finding of infringement if one had filed an ANDA permitting the sale of a range of products, some of which would clearly infringe, so long as the filer made promises to a court that it would keep its activities outside the scope of a patent or filed evidence indicating that such was the case. *See id.* at 1278–80. The only way an infringement defendant under § 271(e)(2) can require a plaintiff to prove facts beyond the ANDA itself under *Glaxo* is if the ANDA is unclear on its face as to its scope. Here, there is no such lack of clarity. The scope of the ANDA, as amended, clearly permits infringement of the '005 Patent.

However, Apotex Defendants in response argue that on March 25, 2014, they filed a second amendment to their ANDA to include a further dissolution limitation of no less than 44% at 15 minutes. If true, this would appear to bring the ANDA outside the scope of all of Ferring's Patents. As noted, *supra*, Apotex Defendants' previous amendment of the ANDA to permit only generic tranexamic acid tablets that would release at least 75% within 45 minutes avoided infringement of the '739 and '106 Patents' limitation of "less than about 70% by weight of the tranexamic acid or a pharmaceutically acceptable salt thereof released at about 45 minutes," but the new limitation does not avoid infringement of the '005 Patent. The release limitations of the '005 Patent are "less than about 40% . . . at about 15 minutes" and "not less than about 50% . . . at about 90 minutes." The ANDA, with its previously added limitation of at least 75% within 45 minutes, avoided infringement of the '739 and '106 Patents but still permitted infringement of the '005 Patent via a hypothetical tablet that released less than 40% at about 15 minutes and at

least 75% within 45 minutes. However, the new amendment's additional limitation of no less than 44% at 15 minutes appears to avoid infringement of the '005 Patent, as well.

Ferring has therefore not shown a likelihood of success on the merits. Ferring has shown a likelihood of irreparable harm via downward pressure on the market price and loss of goodwill that will result from the introduction into the market of an infringing product. The Court is convinced by a preponderance of the evidence that such damage cannot be wholly repaired, and that because this measure of damages is not calculable sum certain, it cannot be repaired via damages. The balance of hardships does not clearly favor either side. Ferring has the right to exclude others from marketing its patented products, but Apotex has the right to market non-infringing competing products. Just as Ferring stands to lose market price and goodwill by Apotex Defendants' infringement, the infringement issue has not yet been finally determined, and Apotex Defendants will themselves be harmed by the imposition of a stigmatizing injunction in a way that is not easily calculable. The balance of hardships therefore does not clearly favor Ferring. The public interest also weighs equally in favor of protecting intellectual property rights and legitimate, non-infringing competition. However the Court were to rule, the drug at issue, and other drugs providing similar relief, will be available to the public from one source or another. The Court denies a TRO but will permit Ferring an opportunity to argue for a preliminary injunction.

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CONCLUSION

IT IS HEREBY ORDERED that the Motion for Temporary Restraining Order (ECF No. 31) is DENIED.

IT IS FURTHER ORDERED that the Preliminary Injunction hearing is set for 09:00A.M., Monday, May 5, 2014, in Reno Courtroom 6, before Judge Robert C. Jones.

IT IS FURTHER ORDERED that the Motion to Shorten Time (ECF No. 32) and Motion for Hearing (ECF No. 37) are DENIED.

IT IS FURTHER ORDERED that the Motions to Seal (ECF Nos. 30, 38) are GRANTED.

IT IS SO ORDERED.

Dated: This 7th day of April, 2014.

ROBERT C. JONES
United States District Judge